IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

VEIN & WELLNESS GROUP, LLC, Plaintiff, v. XAVIER BECERRA, in his capacity as Secretary of the United States Department of Health and Human Services, Defendant.	)	Case No. 1:22-cv-00397-JMC

MEMORANDUM OF LAW IN SUPPORT OF
DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

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Defendant, Xavier Becerra, Secretary of the United States Department of Health & Human Services ("the Secretary" or "HHS"), by and through Erek L. Barron, United States Attorney for the District of Maryland, and Kimberly S. Phillips, Assistant United States Attorney for said district, respectfully submits this Memorandum of Law in Support of his Motion for Summary Judgment, and in support thereof, states as follows:

I. INTRODUCTION

Plaintiff, Vein & Wellness Group, LLC ("Vein & Wellness") seeks judicial review of the final administrative decision of the Secretary pursuant to the Medicare Act (42 U.S.C. § 1395ff(b)(1)(A) incorporating 42 U.S.C. § 405(g)) and pursuant to the Administrative Procedure Act (5 U.S.C. § 706, the "APA"). In 2014 and 2015, Vein & Wellness performed a new type of procedure called mechanical occlusion chemically assisted ablation ("MOCA") to treat Medicare beneficiaries' varicose veins. Compl. ¶ 5. CMS determined these MOCA procedures were not covered under the Medicare program because, at the time Vein & Wellness provided this new treatment, it was not determined to be safe and effective and was considered only experimental or investigational. (*See* Certified Administrative Record, "CAR," at 16-18). The final administrative decision, issued by the Medicare Appeals Council (the "Council") on December 14, 2021 (CAR 14-22) held the MOCA procedures at issue were not medically reasonable and necessary, and, therefore, were not covered by Medicare under 42 U.S.C. § 1395y(a)(1)(A). Judgment should be granted in the Agency's favor upholding the Secretary's final administrative decision because it is legally correct, supported by substantial evidence, not arbitrary or capricious, and does not otherwise violate the APA.

II. STATUTORY AND REGULATORY BACKGROUND

A. Medicare Overview.

The Medicare program was established by Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, to pay for covered medical care provided to eligible aged and disabled persons. Although the Medicare program is comprised of four parts, this case involves only Medicare Part B, a "supplementary medical insurance program for the aged and disabled" from which physicians are paid for professional services rendered. *See* 42 U.S.C. §§ 1395j-1395w-5; 42 C.F.R. Part 410. Part B is a voluntary, supplemental medical insurance program that is financed through monthly fee charges to the beneficiaries and funding from the government. Thus, Part B may be said to resemble "a private medical insurance program that is subsidized in major part by the Federal Government." *Schweiker v. McClure*, 456 U.S. 188, 190 (1982).

The Secretary has overall responsibility for the Medicare program. 42 U.S.C. § 1395hh(a)(1). However, the Centers for Medicare & Medicaid Services ("CMS") is the agency within HHS that is charged with administering the Medicare program. On the Secretary's behalf, CMS enters into contracts with private entities that assist in performing different Medicare program activities. 42 U.S.C. §§ 1395u(a), 1395kk-1(a), 1395ddd. For example, one group of Medicare contractors performs a variety of functions to assure the accuracy of claims' payments, including processing claims and making determinations as to whether claims are payable. 42 U.S.C. § 1395kk-1(a)(4); 42 C.F.R. Part 421. After a Medicare Part B supplier, such as a physician,[1] submits a claim for payment, the Medicare contractor makes an "initial determination" as to whether Medicare will pay in accordance with the statutory and regulatory

[1] The Medicare Act defines the term "supplier" to include "a physician or other practitioner . . . that furnishes items or services under this subchapter." 42 U.S.C. § 1395x(d).

requirements. *See* 42 U.S.C. §§ 1395*l*; 1395u; 42 C.F.R. Part 424.

To expedite claims processing, Medicare contractors generally reimburse providers for services before reviewing the medical records relating to the claims and verifying the claims are valid. *See John Balko & Assocs., Inc. v. Sec'y U.S. Dep't of Health & Human Servs.*, 555 F. App'x 188, 190 (3d Cir. 2014). In practice, Medicare Administrative Contractors pay claims that appear regular on their face, subject to later verification or adjustment, since claims for Medicare reimbursement must normally be made *via* computerized electronic billing submissions which do not permit the Medicare Administrative Contractor to verify first-hand the validity of the claim. 42 C.F.R. § 424.32(d)(2) (requiring electronic billing).

Medicare Administrative Contractors are also required to pay "clean claims" within 30 days after submission in order to avoid paying interest on the claim. 42 C.F.R. § 405.922. A clean claim has no defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment from being made on the claim under this subchapter. 42 U.S.C. § 1395h(c)(2)(B)(i).

Enormous numbers of Medicare claims are submitted for reimbursement each year.[2] The Medicare statute requires that 95 percent of supplier claims are paid within 30 days on a "clean claim" basis. 42 U.S.C. § 1395h(c)(2)(A). The electronic processing of clean claims within very short timeframes reduces administrative costs and ensures prompt payment, thereby encouraging supplier participation. These goals, however, are obtained only through considerable risk: Medicare must rely in substantial part upon the good faith and integrity of suppliers to submit

[2] For example, during 2021, CMS and its contractors processed over one billion Medicare claims. *See* CMS Financial Report FY 2021 (*available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and Reports/CFOReport/Downloads/2021_CMS_Financial_Report.pdf).

only claims that meet reimbursement requirements and that accurately reflect the services provided. Consequently, Medicare providers and suppliers bear the burden of maintaining and producing information to support their payment of claims. *See* 42 C.F.R. § 424.5(a)(6).

In an effort to efficiently process the large volume of Part B claims, Medicare contractors rely, in the first instance, upon the physician's certification of the medical necessity of the services rendered on the CMS claim form. (*See* CMS Form-1500 "Health Insurance Claim Form, *available at* https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-Items/CMS1188854 (last visited June 2, 2022)). The backside of the CMS FORM-1500 explains that, in submitting the claim for payment from federal funds and signing the form, the physician certifies, *inter alia*, that: "5) the services on this form were medically necessary and personally furnished by me or were furnished incident to my professional service by my employee under my direct supervision, except as otherwise permitted by Medicare or Tricare." *Id.* at 2.

To ensure accuracy and to detect fraud and abuse, Medicare contractors continue to work on claims even after payment. Consequently, a Medicare claim remains subject to post-payment review and to reopening. *See generally* 42 U.S.C. § 1395ff(b)(1)(G). CMS uses several types of contractors to identify, calculate, and recover any improper payments, including those that focus on fraud, waste, and abuse detection services. *See* 42 U.S.C. § 1395ddd(b).

Providers submit claims for Medicare reimbursement using the Current Procedural Terminology ("CPT") coding system. *See* HCPCS-General Information (*available at* https://www.cms.gov/medicare/coding/medhcpcsgeninfo (last visited May 27, 2022)). The American Medical Association ("AMA") designed this uniform coding system consisting of descriptive terms and specific codes to identify medical services and procedures furnished by physicians and other health care professionals. *Id.* The CPT code system has been incorporated

into the Healthcare Common Procedural Coding System ("HCPCS") developed by CMS for processing, screening, and paying for Medicare claims. *Id.* Although the CPT codes are useful in the Medicare claims processing system because they identify particular medical services provided, these codes do not determine whether a particular medical service is covered under the Medicare program.[3] The AMA makes decisions regarding the addition, deletion, or revision of CPT codes. Additionally, the AMA publishes annual guidance for CPT coding, including code descriptions, use of modifiers, and coding instructions. *Id.*

B. Medicare Coverage Limited Only to Procedures and Items that are Reasonable and Medically Necessary.

Under the Medicare program, Congress has excluded from coverage all items and services "not reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 411.15(k)(1); *see also* Medicare Program Integrity Manual ("MPIM"), CMS Pub. No. 100-08, Ch 16 "General Exclusions from Coverage," § 20 (excluding services not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member). Congress has delegated to the Secretary the responsibility for deciding whether a particular medical service is reasonable and medically necessary under the Medicare program. 42 U.S.C. § 1395ff(a). Under this delegated authority, the Secretary's decision as to whether a particular medical service is "reasonable and necessary" under the Medicare program, the means by which he implements his decision, whether by promulgating a generally applicable rule or by allowing individual adjudication, are discretionary decisions. 42 U.S.C. § 1395ff(a); *Heckler v. Ringer*, 466 U.S. 602, 617 (1984).

[3] Medicare is a defined benefit program. For any item or service to be covered by Medicare, it must fall into a defined benefit category, must not be statutorily excluded, must be reasonable and necessary under 42 U.S.C. § 1395y(a)(1)(A), and must satisfy other Medicare program requirements for payment.

Congress has authorized two mechanisms to promote consistency in the decisions as to whether a particular medical service is "reasonable and necessary" under the Medicare program—national and local coverage determinations. National coverage determinations are binding decisions issued by the Secretary as to whether a particular item or service will be covered by Medicare on a nationwide basis. 42 C.F.R. § 405.1060(a)(1); *see also* 42 U.S.C. § 1395y(l)(6)(A). Local coverage determinations are non-bindings decisions issued by Medicare Administrative Contractors to guide the application of the "reasonable and necessary" standard in particular claim adjudications. 42 U.S.C. §§ 1395kk-1(a)(1), (4), 1395ff(2)(B).

> When making individual claim determinations, the contractor shall determine whether the item or service in question is covered based on an LCD or the clinical judgment of the medical reviewer. An item or service may be covered by a contractor if it meets all of the conditions listed in § 13.5.1, Reasonable and Necessary Provisions in LCDs below.

MPIM, CMS Pub. No. 100-08, Ch. 13 § 13.3 (eff. 01-15-13).[4]

The "reasonable and necessary" standard is independent of local coverage determinations. If no local coverage determination exists, "Medicare contractors still have an overarching duty to deny claims for items and services that are not 'reasonable and necessary.'" *Agendia, Inc. v. Becerra*, 4 F.4th 896, 900 (9th Cir. 2021). Absent a regulation, a national coverage determination, or a local coverage determination, the Medicare contractor proceeds on a case-by-case basis to determine whether a service is reasonable and necessary. 42 U.S.C. § 1395y(a)(1)(A).

Medicare Contractors shall consider a service to be reasonable and necessary for

[4] The Medicare Program Integrity Manual, Chapter 13 – Local Coverage Determinations, is attached hereto as **Exhibit 1** for ease of access to an archived agency manual provision. Because it consists of the applicable guidance during the relevant time period which was and continues to be publicly available, it is in no way meant to substantively supplement the CAR in this matter.

purposes of 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 411.15(k)(1) if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational. . .; and
- Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is:
    - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member:
    - Furnished in a setting appropriate to the patient's medical needs and condition;
    - Ordered and furnished by qualified personnel;
    - One that meets, but does not exceed, the patient's medical need; and
    - At least as beneficial as an existing and available medically appropriate alternative.

Ex. 1 at § 13.5.1 (eff. 01-15-13).

Additionally, Section 13.7.1 of Ex. 1 sets forth the threshold requirements for the quality of the medical literature necessary to support a determination that a particular service is reasonable and medically necessary for purposes of Medicare coverage:

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and
- General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:
    - Scientific data or research studies published in peer-reviewed medical journals;
    - Consensus of expert medical opinion (i.e., recognized authorities in the field); or
    - Medical opinion derived from consultations with medical associations or other health care experts.

Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The broad range of

> available evidence must be considered and its quality shall be evaluated before a conclusion is reached.

Ex. 1 at § 13.7.1 (eff. 01-15-13).

C. Medicare Administrative Appeals Process.

Pursuant to 42 U.S.C. § 1395ff(a), the Secretary has issued regulations setting forth appeal rights available if a claim does not meet the requirements for Medicare coverage. *See* 42 C.F.R. § 405, Subpart I. In most cases, if the minimum amount in controversy is met, a beneficiary or a provider dissatisfied with the initial determination has the right to appeal Medicare coverage and payment decisions. There are five levels of appeal:

1. Redetermination. A redetermination is an examination of the initial claim decision by the Medicare Administrative Contractor. 42 C.F.R. § 405.940 *et seq.*

2. Reconsideration. A reconsideration is an independent review performed by a Qualified Independent Contractor ("QIC"). 42 C.F.R. § 405.960 *et seq.*

3. ALJ Hearing. If the minimum amount of controversy is met, a provider may request a hearing before an ALJ. 42 C.F.R. § 405.1000 *et seq.*

4. Council Review. If a provider or beneficiary is dissatisfied with an ALJ decision, they may request review by the Council. 42 C.F.R. § 405.1102. The Council may also decide on its own motion to review a decision of the ALJ. 42 C.F.R. § 405.1110.

5. Judicial Review in a United States District Court. Judicial review of the Council's decision may be requested within 60 days of the decision if the minimum amount in controversy is remaining. 42 U.S.C. § 1395ff(b)(1); 42 C.F.R. § 405.1136.

III. STATEMENT OF FACTS

1. Vein & Wellness is a limited liability corporation incorporated in Maryland and specializing in vascular treatments (vein and laser) as well as medical aesthetics.[5] Vein & Wellness changed its name and was, at the time, known as O'Donnell Vein and Medical Spa - Chester. (CAR 1492-1733, 1815-2040, 3438-3657 (Medical Records for Medicare beneficiaries

[5] *See* O'Donnell Vein & Laser website, *available at* https://odonnellveinandlaser.com/ (last visited May 20, 2022).

at issue identified with "O'Donnell Vein and Medical Spa - Chester" letterhead)).

2. Between April 2014 through December 2015, Vein & Wellness performed 158 MOCA procedures on Medicare beneficiaries' legs to treat their varicose veins. (Compl. at ¶ 5; *see also* **Exhibit 2** (chart containing CAR citations for medical records documenting the MOCA procedures were performed for the Medicare beneficiaries at issue); CAR 2122 (Vein & Wellness Prehearing Brief before the ALJ hearing)).[6]

3. Vein & Wellness performed the MOCA procedures on the beneficiaries' large veins greater than 6mm diameter – the main saphenous veins and the saphofemoral junction or saphopopliteal junction. (CAR 275; *see also* CAR 1492-1733, 1815-2040, 3438-3657 (operative reports)).

4. The operative reports describe a common procedure description, "mechanical occlusion with chemical assistance." (CAR 276 (medical review of operative reports); *see also* CAR 1492-1733, 1815-2040, 3438-3657 (operative reports)). Additionally, the procedure notes all include the following statement "the catheter was pulled back approximately 1.5 mm per second, with infusion of the STS to attain occlusion of the abnormal, saphenous vein." (*Id.*) STS is an abbreviation for Sodium Tetradecly Sulfate, a sclerosing agent that works by closing the varicose vein through scarring. (*Id.*)

5. In 2014, the MOCA procedure was a new technology for treatment of varicose veins which combined two different types of preexisting treatment – mechanical ablation with a chemical sclerosing agent. (CAR 36 (CMS Referral for Own Motion Review quoting October 2014 AMA CPT Guidance)).

[6] Exhibit 2 is included herein only as a guide to the relevant citations in the CAR; it is not intended to substantively supplement the CAR in this matter.

6. In 2014 and 2015 there was no CPT code that captured the procedural code for the MOCA procedure. (CAR 35 (The AMA CPT Guidance published in August 2014 noting that the procedure description for endomechanical ablation of a varicose vein "does not conform to any of the current . . . CPT venous ablation code descriptions (36468-36479). In addition, it is also not a venous embolization procedure, and therefore, does not qualify to be reported with the venous embolization CPT code 37241. . . [ ] . . . Based on the procedural description of endo-mechanical ablation, code 37799, *Unlisted procedure, vascular surgery*, is currently the most appropriate CPT code to report endomechanical ablation of a varicose vein."))

7. Vein & Wellness submitted claims for reimbursement under Medicare Part B for the MOCA procedures using CPT Code 37241. (CAR 14 (Council Decision); CAR 2123 (Vein & Wellness Prehearing Brief before ALJ Hearing); CAR 4686 (ALJ Hearing, lines 2-4)).

8. CMS's Medicare contractor, Novitas Solutions, Inc. ("Novitas") initially paid all the Medicare Part B claims at issue within 30 days of submission of the claims as required by 42 C.F.R. § 405.922. (CAR 14-15 (Council Decision); CAR 25 (CMS Referral for Own Motion Review By Council)).

9. In 2016, SafeGuard Services, LLL, Medicare's New England Benefit Integrity Safeguard Contractor ("NE BISC") and a Program Safeguard Contractor ("PSC") conducted a post-payment review of Vein & Wellness's claims for 106 beneficiaries because NE BISC proactive data analysis identified the provider as potentially billing procedure code 37241. (CAR 25 (CMS Referral for Own Motion Review By Council)).

10. Based on the post-payment medical review of Vein & Wellness's claims for 106 beneficiaries, NE BISC found Medicare had overpaid Vein & Wellness by approximately $941,111.96. (*Id.*)

11. Based on the NE BISC post-payment medical review, Novitas determined the payments for these beneficiaries were made in error. *Id.* Novitas explained: "[b]ased on Medicare guidelines, the service(s) on the original claim was not considered medically necessary. This decision is based on either the documentation that was submitted or the failure by the physician/supplier to furnish information that was requested to support the claim." (*Id.* (quoting Novitas' Initial Determination denying the reimbursement claims)).

12. Once CMS denied the Medicare Part B claims, Vein & Wellness pursued multiple levels of administrative appeal.

13. Redetermination.

a. Vein & Wellness appealed the initial claim denial by requesting Redetermination from Novitas, asserting that "each beneficiary suffered from the condition for which they were treated." *Id.*; *see also* **Exhibit 3** (chart identifying Redetermination decision citations for each Medicare beneficiary).[7]

b. Novitas upheld the claim denials for the MOCA procedures because "the information provided did not support the need for this service or item." (*See, e.g.*, CAR 329 (Redetermination for E.S.); *see also* Ex. 3). Novitas explained, based on the medical literature, the MOCA procedure is not considered effective for large veins greater than 6mm diameter or for the main saphenous veins. (CAR 330). Novitas specifically cited to LCD's L32678 and L34924 in support of the claim denials. (*Id.*)

14. Reconsideration.

a. Vein & Wellness appealed the adverse Redetermination decisions by requesting

[7] Exhibit 3 is included herein only as a guide to the relevant citations in the CAR; it is not intended to substantively supplement the CAR in this matter.

Reconsideration from the QIC, C2C Innovative Solutions, Inc. ("C2C"). (*See* Ex. 3).

b. The Reconsideration decisions were adverse and upheld the claim denials. *Id.* C2C concluded the MOCA services "did not meet the requirements to be considered reasonable and necessary in the treatment of the patients." (*See, e.g.*, CAR 261 (Reconsideration for various Medicare beneficiaries listed at CAR 262-266); *see also* Ex. 3).

c. C2C upheld the claim denials on two bases: (1) Vein & Wellness billed the services under an incorrect CPT code, 37241, that did not apply to the MOCA procedure; and (2) the LCD excludes coverage for sclerotherapy involving veins larger than 6mm in diameter. (*See* CAR 26-27 (CMS Referral for Own Motion Review By Council)).

15. ALJ Hearing.

a. Vein & Wellness requested an ALJ Hearing. (CAR 2151-2202). A pre-hearing conference was held on Monday April 19, 2021 before Senior Attorney Advisor, Courtney Eastman. (CAR 4659-4675). The ALJ Hearing was held on May 17, 2021 before ALJ Lori L. May. (CAR 4676-4697).

b. On August 13, 2021, ALJ Lori L. May issued three separate decisions, *Vein &Wellness Group LLC*, OMHA Appeal Nos. 3-5712041048 (CAR 164-178), 3-5712041192 (CAR 1771-1785), 3-5736021004 (CAR 3400-3413) covering all the administrative appeals for each of the beneficiary claim denials at issue. (*See* Ex. 3 (citing to each of the three ALJ decisions and indicating which decision applies to each respective beneficiary claim denial)).

c. The holding and reasoning of all three ALJ decisions was the same. (CAR 164-178, 1771-1785, 3400-3413). The ALJ held that Vein & Wellness billed Medicare properly for the MOCA procedures by using CPT code 37241 because that was the most appropriate code in effect on the dates of service at issue. (CAR 174, 1781, and 3410). The ALJ further held that

the LCDs that the QIC had relied on in rendering the Reconsideration decisions (L3268 and L34924) were inapplicable. (*Id.*) Finally, the ALJ held that the medical records showed that the MOCA procedures were medically necessary for treating the beneficiaries' varicose veins. (*Id.*)

16. CMS Referral for Own Motion Review by the Medicare Appeals Council.

a. On October 8, 2021 CMS submitted a Referral for Own Motion Review of the three respective ALJ decisions *Vein &Wellness Group LLC*, OMHA Appeal Nos. 3-5712041048, 3-5712041192, 3-5736021004. (CAR 23-163). CMS's Referral was based on its allegation that the ALJ decisions contained material legal errors. (*Id.*)

17. Council Review.

a. On December 14, 2021, the Council, under the authority of 42 C.F.R. § 405.1110, on its own motion, decided to review the three respective ALJ decisions *Vein & Wellness Group LLC*, OMHA Appeal Nos. 3-5712041048, 3-5712041192, 3-5736021004 and issued a decision, *Vein and Wellness Group, LLC,* Medicare Appeals Council Docket No. M-22-53 (Dec. 14, 2021). (CAR 11-22).

b. The Council reversed the ALJ's decision that Medicare covered most of the MOCA procedure claims at issue. (CAR 14-15). However, the Council upheld the ALJ's coverage denials for a handful of MOCA procedures Vein & Wellness provided to the following Medicare beneficiaries due to insufficient records: E.C. on February 2, 2015; T.G. on June 6, 2014; M.L. on June 6, 2015; J.M (HICN ending in NJ12) on October 7, and 14, 2015; and A.R. on July 24, 2014. (CAR 14-15).

c. The Council also upheld the ALJ's determination that the LCDs L32678 and L34924 are inapplicable to these cases because the versions in effect on the dates at issue did not address the MOCA procedure at issue. (CAR 15).

d. The Council held that, because no LCDs were on point, the ALJ materially erred as a matter of law in failing to properly evaluate on a case-by-case basis whether the services at issue were reasonable and medically necessary in accordance with 42 U.S.C. § 1395y(a)(1)(A) based on all of the conditions listed in MPIM, CMS Pub. No. 100-08, Ch. 13 § 13.5.1. *See* Ex. 1.

e. The Council explained the ALJ was required to assess whether the MOCA procedures at issue were "safe and effective, not experimental or investigational, and appropriate based on the strongest medical evidence possible. MPIM, Ch. 13 §§ 13.3, 13.5.1, 13.7.1."[8] (CAR 16-17). The Council also noted, as a Medicare supplier, Vein & Wellness, bore the burden of maintaining and producing information to support their claims for Medicare reimbursements. 42 C.F.R. § 424.5(a)(6). Accordingly, the Council held the ALJ erred in finding the MOCA procedures were reasonable and medically necessary because "the records do not include any published authoritative evidence, or support any general acceptance by the medical community, that the service was safe and effective, not experimental or investigational and appropriate for the beneficiaries on the dates they received their MOCA procedures." (CAR 17).

f. The Council held the MOCA procedures furnished to the Medicare beneficiaries were not reasonable and medically necessary, and, therefore, not covered by Medicare. (CAR 14). The Council concluded the MOCA procedure was experimental at the time the services were provided based on the fact that LCD L34924 determined the procedure was experimental even in 2017. (CAR 17). Additionally, the Council found the 2017 draft LCD contained a

[8] Such evidence includes published authoritative evidence from definitive randomized clinical trials or other definitive studies, and general acceptance by individuals, or even limited groups, does not indicate general acceptance by the medical community. Ex. 1 § 13.7.1. The MPIM clarifies that acceptance by individuals, or even limited groups, does not indicate general acceptance by the medical community. *Id.*

comprehensive medical review of the clinical studies and research available for the MOCA procedure which concluded that it was experimental, investigational, or unproven as therapy for varicose veins. (*Id.*)

g. The Council held Vein & Wellness was financially liable for the non-covered services and was not entitled to a waiver of the overpayments under 42 U.S.C. § 1395gg.[9]

18. On December 27, 2021, Vein & Wellness submitted to the Council a Request to Reopen and to Reconsider the decision, *Vein and Wellness Group, LLC,* Medicare Appeals Council Docket No. M-22-53 (Dec. 14, 2021). (CAR 1-10).

19. On February 16, 2022, Vein & Wellness timely filed the Complaint in the instant case in accordance with 42 U.S.C. § 1395ff(b)(1)(A) and 42 U.S.C. § 405(g) requesting judicial review of the final administrative decision of the Secretary. (*See* Compl.).

20. On May 2, 2022, the Council issued an Order Denying the Request for Reopening because Vein & Wellness appealed the Council's December 14, 2021 decision to district court before the Council could respond to the Request and, as a result, the Council no longer has jurisdiction. (CAR 4733-4738).

21. Because the Council denied Vein & Wellness's Request for Reopening, the December 14, 2021 decision issued by the Council constitutes the Secretary's final administrative decision for purposes of 42 U.S.C. § 1395ff(b)(1)(A). (CAR 14-22).

[9] As the Council noted, Vein & Wellness never argued it was entitled to a waiver of the overpayment during the administrative appeal process. (CAR 18). Accordingly, the Council's determination on this issue is administratively final and not subject to appeal because of Vein & Wellness's failure to exhaust its administrative remedies with respect to this issue. 42 U.S.C. § 1395ff(b)(1)(A) (providing for judicial review only to the extent administrative remedies have been exhausted).

IV. STANDARD OF REVIEW

This Court's review of the Secretary's final decision in this case is governed by 42 U.S.C. § 1395ff(b)(1)(A) which specifically incorporates 42 U.S.C. § 405(g). Under the judicial review standard governed by 42 U.S.C. § 405(g), the district court reviews the Secretary's final decision "based solely on the administrative record, and the Secretary's findings of fact, if supported by substantial evidence, shall be conclusive." *MacKenzie Med. Supply, Inc. v. Leavitt*, 506 F.3d 341, 346 (4th Cir. 2007) (citing 42 U.S.C. § 1395ff(b)(1)(A)); *see also* 42 C.F.R. § 405.1136(f)(1) (providing that the standard of review requires, under 42 U.S.C. § 405(g), that the findings of the Secretary of HHS as to any fact, if supported by substantial evidence are conclusive). Under the narrow jurisdiction of 42 U.S.C. § 405(g), the Court has the power only to "affirm[], modify[], or reverse[] the [Secretary's] decision[.]" 42 U.S.C. §405(g).[10]

In addition, judicial review of the Secretary's decision is governed by the APA, which provides that final agency action shall be upheld absent a finding that it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," "without observance of procedure required by law," or is otherwise "unsupported by substantial evidence." 5 U.S.C. §§ 706(2)(A), (D), (E). The Court's review under the APA is "limited" and "narrow." *Flynn v. U.S. Secs. and Exch. Comm'n*, 877 F.3d 200, 204 (4th Cir. 2017); *Ohio Valley Envtl. Coal., Inc. v. U.S. Army Corps of Eng'rs*, 828 F.3d 316, 321 (4th Cir. 2016).

In reviewing a final agency action under the APA, the Court must accord substantial deference to the final agency action and presume it valid. *Friends of Back Bay v. U.S. Army Corps of Eng'rs*, 681 F.3d 581, 587 (4th Cir. 2012). The Fourth Circuit has explained:

[10] Under 42 U.S.C. § 1395ii, which makes Section 405(g) applicable to the Medicare program, any reference in Section 405(g) to the Commissioner of Social Security or the Social Security Administration is considered a corresponding reference to the HHS Secretary or to HHS.

> Because 'resolution of this dispute involves primarily issues of fact' and 'requires a high level of technical expertise,' the Court must defer to 'the informed discretion of the responsible federal agencies.". . . [ ] . . . Nevertheless, the Court must conduct a 'searching and careful' review to determine whether the agency's decision 'was based on a consideration of the relevant factors and whether there has been a clear error of judgment.'

Sierra Club v. U.S. Dep't of the Interior, 899 F.3d 260, 270 (4th Cir. 2018) (citations omitted).

The Supreme Court has explained that the APA's arbitrary and capricious standard "requires that agency action be reasonable and reasonably explained. . . [ ] . . . A court simply ensures that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision. *F.C.C. v. Prometheus Radio Project*, 141 S.Ct. 1150, 1158 (2021) (citations omitted). The court "must ensure that the agency has examined the relevant data and articulated a satisfactory explanation for its action." *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 513 (2009).

Review under the arbitrary and capricious standard is highly deferential, with a presumption in favor of finding the agency action valid. *Ohio Valley Envtl. Coal. v. Aracoma Coal Co.*, 556 F.3d 177, 192 (4th Cir. 2009). However, "[t]he arbitrary-and-capricious standard does not reduce judicial review to a rubber stamp of agency action." *Sierra Club*, 899 F.3d at 270. "Agency action is arbitrary and capricious if the agency relies on factors that Congress did not intend for it to consider, entirely ignores important aspects of the problem, explains its decision in a manner contrary to the evidence before it, or reaches a decision that is so implausible that it cannot be ascribed to a difference in view." *Ergon-West Virginia v. U.S. Envtl. Prot. Agency*, 896 F.3d 600, 609 (4th Cir. 2018) (citing *United States v. FIV Alice Amanda*, 987 F.2d 1078, 1085 (4th Cir. 1993)).

Summary judgment is warranted when there is no genuine dispute as to any material fact

and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). Because all the facts are set forth in the administrative record in a case brought under the Medicare Act (42 U.S.C. § 1395ff(b)(1)(A) and 42 U.S.C. § 405(g)) and under the APA, there are no factual disputes to resolve, and the entire case is a question of law, *i.e.*, whether the agency decision is supported by the administrative record and consistent with the APA. *See Hyatt v. U.S. Patent & Trademark Office*, 146 F. Supp. 3d. 771, 780 (E.D. Va. 2015).

V. ARGUMENT

A. The Secretary's Final Administrative Decision Should be Upheld Because it is Legally Correct, Supported by Substantial Evidence, and Not Arbitrary or Capricious.

1. The Secretary's Final Administrative Decision is Legally Correct and Supported by Substantial Evidence.

As explained more fully above, Congress has excluded from Medicare coverage all items and services "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). The Medicare statute has granted the Secretary broad discretion to determine whether specific medical services are reasonable and medically necessary under the Medicare program. 42 U.S.C. § 1395ff(a); *Heckler*, 466 U.S. at 617. The Secretary's implementing regulation at 42 C.F.R. § 411.15(k)(l) similarly excludes from Medicare coverage all services that are not reasonable and necessary.

Pursuant to that statutory and regulatory authority, the Secretary has interpreted this exclusion to mean that services are reasonable and necessary for purposes of Medicare coverage only if they are: safe and effective; not experimental or investigational; appropriate, including the duration and frequency considered appropriate for the item or service, in terms of whether it is: (1) furnished in accordance with accepted standards of medical practice for the diagnosis or

treatment of the patient's condition or to improve the function of a malformed body member; (2) furnished in a setting appropriate to the patient's medical needs and condition; (3) ordered and furnished by qualified personnel; (4) one that meets, but does not exceed, the patient's medical need; and (5) at least as beneficial as an existing and available medically appropriate alternative. Ex. 1 at § 13.5.1.

The Secretary is entitled to deference under *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945) with respect to his interpretation of the regulation at 42 C.F.R. § 411.15(k)(1) that implements the Medicare Act's "reasonable and necessary" standard. This principle requires courts to give an agency's view of its own regulations "controlling weight unless it is plainly erroneous or inconsistent with the regulation." *Id.* The Supreme Court has emphasized the importance of careful adherence to this standard in the Medicare context, which deals with "a complex and highly technical regulatory program, in which the identification and classification of relevant criteria necessarily requires significant expertise and entails the exercise of judgment grounded in policy concerns." *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994). Here, the Secretary's interpretation of the "reasonable and necessary" standard applied in the context of Medicare coverage determinations is not plainly erroneous or inconsistent with the regulation. *Compare* 42 C.F.R. § 411.15(k)(l), *with* Ex. 1 at § 13.5.1. Accordingly, the Secretary's interpretation of the "reasonable and necessary" standard at 42 C.F.R. § 411.15(k)(l) is reasonable and should be upheld.

Additionally, the Secretary's interpretation of 42 U.S.C. § 1395y(a)(1)(A) of Medicare statute as published in the MPIM Ch. 13 § 13.5.1 is entitled to deference under *United States v. Mead Corp.*, 533 U.S. 218, 226-27 (2001) and *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). Under *Skidmore*, the weight that courts afford an agency's interpretation "depend[s] upon the

thoroughness evident in [the agency's] consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade." *Skidmore*, 323 U.S. at 140. The court later distilled that principle to mean that an interpretive rule is "entitled to respect only to the extent it has the power to persuade." *Gonzalez v. Oregon*, 546 U.S. 243, 255 (2006); *see also Perez v. Cuccinelli*, 949 F.3d 865, 877 (4th Cir. 2020) ("Absent eligibility for *Chevron* deference, agency interpretations are only given a level of respect commensurate with their persuasiveness.") To gauge a rule's persuasiveness under *Skidmore*, courts look to "the degree of the agency's care, its consistency, formality, and relative expertness, and to the persuasiveness of the agency's position." *Mead*, 533 U.S. at 228.

In applying the *Mead/Skidmore* factors to the Secretary's interpretation of 42 U.S.C. § 1395y(a)(1)(A) published in the MPIM Ch. 13 § 13.5.1, the interpretation is entitled to deference because of the agency's considerable experience and expertise in rendering Medicare coverage decisions. *See Almy v. Sebelius*, 679 F.3d 297, 302-03 (4th Cir. 2012) (noting how a reviewing court must be at its most deferential when reviewing the Secretary's determination of what is "reasonable and necessary" because it requires a significant degree of medical judgment, constitutes an examination of a scientific determination, and is, therefore, considerably different from reviewing simple findings of fact). Here, the Medicare Appeals Council has greater expertise and stands in a better position than this Court to make the technical and policy judgments necessary to administer the complex regulatory program at issue. *See Talk America, Inc. v. Mich. Bell. Tel. Co.*, 564 U.S. 50, 69 n.7 (2011) (explaining that a "technical factual dispute simply underscores the appropriateness of deferring" to agency decisions); *see also Rehab. Ass'n of Va., Inc. v. Kozlowski*, 42 F.3d 1444, 1450 (4th Cir. 1994) (noting that the Medicare statute is "among the most completely impenetrable texts within human experience").

The Secretary's interpretation is also entitled to deference because it is persuasive that Medicare, like any other health insurance program, would define reasonable and necessary services subject to coverage as only those services that are "furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition, "safe and effective," and "not experimental or investigational." Ex. 1 at § 13.5. In sum, the Secretary's interpretation of 42 U.S.C. § 1395y(a)(1)(A) of Medicare statute as published in the MPIM Ch. 13 § 13.5.1 is entitled to deference because it is persuasive and because it is informed by the agency's considerable experience and expertise. *See West Virginia CWP Fund v. Stacy*, 671 F.3d 378, 388-90 (2011) (court deferred to interpretation of Director of Office of Workers' Compensation Programs that operative filing date for determining eligibility for automatic survivors' benefits under applicable statute was date survivor's claim was filed because interpretation was persuasive given plain language of statute and consistency of interpretation with larger statutory framework); *Cunningham v. Scibana*, 259 F.3d 303, 306-09 (4th Cir. 2001) (holding the Bureau of Prisons' decision to classify a criminal's crime as violent in all cases was persuasive "because that decision is supported by experience and sound and consistent reasoning").

In the context of the Secretary's persuasive interpretation of 42 U.S.C. § 1395y(a)(1)(A) of the Medicare statute as published in Ex. 1 at § 13.5.1, the Secretary's determination that the MOCA procedures at issue in the instant case were not covered under the Medicare program was legally correct. Where a provider or supplier fails to produce evidence sufficient to demonstrate that the treatment or services at issue were *not* experimental, the Secretary is legally authorized to deny Medicare coverage for those treatments or services as not reasonable or medically necessary under 42 U.S.C. § 1395y(a)(1)(A). *Almy*, 679 F.3d at 305-07. In *Almy*, a medical

device manufacturer challenged the Secretary's denial of coverage for a device used to treat osteoarthritis of the knee. *Id.* at 301-02. However, the device manufacturer failed to produce credible and credited evidence sufficient to demonstrate the treatment/services were *not* experimental. *Id.* at 305-307. After according proper deference to the Secretary's interpretation of the Medicare statute and of her own regulation, the Fourth Circuit held that the Secretary properly excluded the treatment/services at issue as not reasonable or necessary under the Medicare program. *Id.*

Just as the device manufacturer in *Almy* failed to produce sufficient documentation to demonstrate the reasonableness and medical necessity of the treatment/services at issue, here Vein & Wellness failed to produce sufficient documentation to demonstrate the reasonableness and medical necessity of the MOCA services at issue. (CAR 17 (Council decision noting "the records do not include any published authoritative evidence, or support any general acceptance by the medical community, that the service was safe and effective, not experimental or investigational, and appropriate for the beneficiaries on the dates they received their MOCA procedures")). Accordingly, analogous to Fourth Circuit decision in *Almy,* this Court should hold the Secretary correctly determined the MOCA procedures at issue were not reasonable and medically necessary because at the time the services were provided they were not demonstrated to be safe and effective and, instead, were considered experimental or investigational. *See Almy*, 679 at 305-07; Ex. 1 at § 13.5.1.

Moreover, the Secretary's determination that the MOCA procedures at issue were not reasonable or medically necessary is supported by substantial evidence. The record shows that Vein & Wellness produced only medical records documenting that the MOCA procedure was performed for various Medicare beneficiaries and the context under which the procedure was

performed. (CAR 1492-1733, 1815-2040, 3438-3657 (operative reports)). However, Vein & Wellness did not produce evidence demonstrating that, at the time the services were provided in 2014 and 2015, the MOCA procedure was generally accepted by the medical community. Nor did Vein & Wellness produce authoritative medical evidence or proof supporting its claim that the MOCA procedure was reasonable and medically necessary under the Medicare program. Accordingly, Vein & Wellness did not meet its burden of producing information sufficient to support its claims for Medicare reimbursement regarding the MOCA procedures at issue. 42 C.F.R. § 424.5(a)(6); Ex. 1 at § 13.7.1 (describing evidence required to demonstrate services are reasonable and necessary).

The record further shows that, at the time the services at issue were provided in 2014 and 2015, the MOCA procedure was a new technology and, as a result, there was a lack of published authoritative evidence from definitive randomized clinical trials and other definitive studies supporting its reasonability and medical necessity. For example, because the MOCA procedure was a "new technology," no CPT code even existed for the MOCA procedure prior to 2017.[11] (CAR 34-36, 173, 1780, and 3409). Similarly, because the MOCA procedure was a "new technology," no LCD existed for the MOCA procedure prior to 2017. When LCD L34924 was drafted in 2017, CMS concluded that the MOCA procedure was experimental. (CAR 17). The

[11] The ALJ ignored the fact that no CPT existed for the MOCA procedure at the time the services were provided in 2014 and 2015. Instead, the ALJ accepted Vein & Wellness's assertion that it billed the services appropriately to the Medicare program because it billed the services under the closest CPT code that was in effect at the time (*i.e.*, CPT code 37799 which is a general CPT code designated for an unlisted procedure involving vascular surgery). (CAR 34 (describing CPT code 37799); CAR 172-173, 1779-1780, 3408-3409 (ALJ decisions)). However, the ALJ decisions miss the significance of the fact that no CPT existed for the MOCA procedure at the time the services were provided. The fact that no CPT existed for the MOCA procedure is directly related to the fact that, at the time the services were provided, the procedure was so new that there was insufficient medical evidence to demonstrate the MOCA procedure was safe, effective, and not experimental. (CAR 17).

2017 draft of LCD L34924 included a medical review of the clinical studies and research available for the MOCA procedure which led CMS to conclude the procedure was "considered experimental, investigational, or unproven" as therapy for varicose veins. (*Id.*) Because the MOCA procedure was experimental, investigational, and unproven in 2017, it clearly was experimental, investigational, and unproven at the time the services were provided several years earlier in 2014 and 2015. (*See* CAR 38-39 (noting that CMS did not cover the MOCA procedure under an LCD supported by the requisite evidence of medical efficacy and general acceptance in the medical community until December 27, 2020)).

Finally, the record also demonstrates that, to the extent the MOCA procedure is safe and effective, it is only safe and effective for the treatment of small to medium-sized veins (3-6mm diameter). (CAR 25-30 (CMS Referral for Own Motion Review by Council), 4812 (LCD L34924), 4829 (LCD L32678)). As previously noted, when performing the MOCA procedures on the Medicare beneficiaries at issue, Vein & Wellness performed the procedures on the beneficiaries' large veins greater than 6mm diameter – the main saphenous veins and the saphofemoral junction or saphopopliteal junction. (CAR 275; *see also* CAR 1492-1733, 1815-2040, 3438-3657 (operative reports)). Accordingly, the Secretary also correctly determined the MOCA procedure was not reasonable and medically necessary because the services were not furnished in accordance with accepted standards of medical practice for treatment of the patient's condition (*i.e.*, treatment of varicose veins involving large veins greater than 6mm in diameter). (*Id.*)

Courts have upheld judgments by the Secretary finding medical care and equipment to be unreasonable or unnecessary where there was insufficient evidence to support Medicare coverage. *See, e.g.*, *Goodman v. Sullivan*, 891 F.2d 449, 451 (2d. Cir. 1989) (denying coverage

of MRIs before they were determined to be safe and effective instead of experimental, investigative, and unproven); *Friedrich v. Sec'y of Health & Human Servs*., 894 F.2d 829, 831 (6th Cir. 1990) (excluding coverage for atherosclerosis therapy); *Santurce Pharm. Corp. v. Sec'y of Health & Human Servs.*, No. 104CV254DA, 2005 WL 1711661, at *3 (N.D. Miss. July 25, 2005) (upholding an ALJ's determination that DME was not covered because medical necessity had not been properly documented); *Gulfcoast Med'l Supply, Inc. v. Sec'y, U.S. Dep't of Health & Human Servs.*, 8:04-cv-2610, 2005 WL 3934860, at *7-8 (M.D. Fla. Nov. 16, 2005) (affirming denial of coverage for power wheelchairs because of insufficient documentation of medical necessity); *Smith v. Thompson*, 210 F.Supp.2d 994, 999-1000 (N.D. Ill. 2002) (excluding coverage of cryosurgical ablation of prostrate as not reasonable or medically necessary because the evidence was not yet sufficient to demonstrate the effectiveness of the procedure). Just as with these cases, this Court should uphold the Secretary's denial of Medicare coverage for the MOCA procedures at issue because there is insufficient documentation and evidence supporting medical necessity.

2. The Secretary's Final Administrative Decision is Not Arbitrary or Capricious.

The Secretary's decision to deny Medicare coverage for the MOCA procedures performed in 2014-2015 was not arbitrary and capricious in violation of 5 U.S.C. § 706(2)(A) even though the Secretary has since decided to allow coverage for the procedure in certain limited circumstances starting in 2020. While it is true that the Medicare program did not cover MOCA services in 2014 and 2015, Medicare now covers MOCA services based on new research which demonstrates the procedure is safe, effective, and not experimental "for ablation of incompetent saphenous veins for the treatment of patients with symptomatic CEAP clinical classification C2 to C6 disease." (CAR 38 (describing how LCD L34924 was revised to

expressly cover MOCA services effective December 27, 2020 but, only in certain limited circumstances)).

The Secretary's decision to cover the MOCA procedure in 2020 was a reasonable decision that was rationally based on a medical review of the literature and a determination that the procedure was now safe and effective and not experimental within the specific parameters set forth in the LCD. *See* Ex. 1 at § 13.7.1 (describing the necessary evidentiary support required to support an LCD including published authoritative evidence based on randomized clinical trials and other definitive studies as well as general acceptance by the medical community). As previously explained, prior to 2020, CMS had determined the MOCA procedure was still considered experimental, investigational, or unproven treatment for varicose vein ablation. (CAR 17). Thus, the absence of sufficient evidentiary support amply explains the Secretary's decision not to cover the MOCA procedure in 2014 and 2015. And, the advent of sufficient evidentiary support in 2020 explains the Secretary's decision to cover the MOCA procedure in certain circumstances in 2020. Thus, the Secretary's rationale for covering the MOCA procedure in 2020 and for denying Medicare coverage prior to that time was reasonable and reasonably explained for purposes of the APA's deferential arbitrary and capricious standard. *See Prometheus Radio Project*, 141 S.Ct. at 1160 (holding the FCC's analysis used to repeal three rules was not arbitrary and capricious because it was reasonable and reasonably explained).

Additionally, Vein & Wellness suggests the final administrative decision of the Secretary is arbitrary and capricious because "[n]either the MAC nor QIC denied the claims asserting that the MOCA procedure is not covered." (CAR 4722 (Vein & Wellness Exceptions to CMS's Referral for Own Motion Review by the Medicare Appeals Council)). Vein & Wellness is incorrect as a matter of fact and law. Medicare denied the claims at issue because it determined

the MOCA services were not reasonable or medically necessary in accordance with 42 U.S.C. § 1395y(a)(1)(A). (*See e.g.*, CAR 3837-3840, 3716-3728; *see also* CAR 25-27; Ex. 3 (chart identifying citations for the Redetermination and Reconsideration decisions for each Medicare beneficiary)). Additionally, Vein & Wellness's assertion is legally incorrect because lower-level administrative appeal decisions are non-binding and, therefore, would not reflect inconsistency in the Medicare program.

The record shows that the Medicare program did, in fact, deny coverage for the procedures at issue because it determined the services were not reasonable or necessary. (*See, e.g.*, CAR 3837-3840 (Medicare Administrative Contractor determination upholding the claims denial as not medically necessary); CAR 3716-3724 (QIC determination upholding the claims denial as not "reasonable and necessary in the treatment of the patients")).

Moreover, lower-level administrative decisions are binding only if the provider or supplier fails to appeal them. 42 C.F.R. §§ 405.928 (initial determination non-binding if appealed), 405.958 (redetermination non-binding if appealed), 405. 978 (reconsideration non-binding if appealed), 405.1048 (ALJ decision non-binding if appealed), 405.1130 (Council decision non-binding if appealed). Vein & Wellness appealed these lower-level administrative decisions, and they were not binding. 42 C.F.R. §§ 405.928, 405.958, and 405.978. Accordingly, none of the lower-level administrative appeal decisions issued in the instant case undermine the consistency of the Secretary's position. *See Cmty. Care Found. v. Thompson*, 318 F.3d 219, 227 (D.C. Cir. 2003) ("There is no authority for the proposition that a lower component of a government agency may bind the decision making of the highest level. . . . [E]ven if these cases were found to evince internal inconsistency at a subordinate level, the [agency] itself would not be acting inconsistently."); *see also Ergon-West Virginia*, 896 F.3d at

609 (holding that agency action is arbitrary and capricious only if agency relied on factors Congress did not intend for it to consider, ignores important aspects of the problem, contradicts the evidence, or reaches an implausible decision).

Vein & Wellness further suggests the Secretary's final administrative decision is arbitrary and capricious because the Medicare contractor had covered the MOCA procedure in the past when billed using CPT code 37241. (CAR 17 (noting that the records include prior favorable reconsiderations)). As the Council explained, even if the Medicare contractor allowed Medicare coverage for MOCA procedures in 2014-2015 in a few instances (CAR 2124-2147), this does not change the Medicare requirements, and the court may not compound CMS's purported errors by compelling the agency to allow coverage for MOCA procedures when it is clear that such procedures were not reasonable or medically necessary at the time they were provided. *Beverly Health & Rehab. Servs. v. Thompson*, 223 F. Supp. 2d 73, 112 (D.D.C. 2002) (selective enforcement does not bar future enforcement action); *see also PG Pub. Co. v. Aichele*, 705 F.3d 91, 115 (3d. Cir. 2013). With respect to CMS's authority to enforce the statutory requirements for participation in Medicare, "any prior laxity in enforcement cannot deprive the agency of its ability to sanction a facility that is not in substantial compliance." *Beverly Health*, 223 F. Supp. 2d at 112. Accordingly, CMS's handling of other Medicare claims cannot undercut Vein & Wellness's responsibility to demonstrate it was in compliance with the applicable legal requirements or remove CMS's authority to take actions it is authorized to take by statute.

As discussed more fully above, Plaintiff's assertion that the final administrative decision is arbitrary and capricious in violation of the APA is without merit. Plaintiff has failed to allege any facts or circumstances that would support a finding that the final administrative decision is arbitrary and capricious. It has not demonstrated that the final administrative decision relied on

factors that Congress did not intend for it to consider, entirely ignored important aspects of the problem, explained its decision in a manner contrary to the evidence before it, or reached a decision that is so implausible that it cannot be ascribed to a difference in view. *See Ergon-West Virginia*, 896 F.3d at 609.

B. Vein & Wellness's Additional Claims Provide No Basis for Disturbing the Final Administrative Decision of the Secretary.

1. Medicare Did Not Unlawfully Withhold or Unreasonably Delay Agency Action in Violation of 5 U.S.C. § 706(1).

Vein & Wellness alleges the Secretary's decision as unlawfully withheld or unreasonably delayed under 5 U.S.C. § 706(1) of the APA. Compl. at ¶ 34. However, because the Secretary has already taken "final agency action" in issuing the "final administrative decision" at CAR 14-22, he cannot be considered to have "unreasonably delayed" his decision such that this Court must compel agency action under 5 U.S.C. § 706(1). *South Carolina v. United States*, 907 F.3d 742, 759 (4th Cir. 2018) (holding that "claims of unreasonable delay can be properly addressed through a mandamus proceeding" rather than under 5 U.S.C. § 706(1)); *Telecomms. Research & Action Ctr. v. Fed. Commc'ns Comm'n*, 750 F.2d 70, 79 (D.C. Cir. 1984) ("Claims of unreasonable agency delay clearly fall into that narrow class of interlocutory appeals from agency action over which the court should appropriately exercise its jurisdiction.")

Nor was the Secretary's final decision unlawfully withheld under 5 U.S.C. § 706(1) of the APA. A court can compel agency action under this section only if there is "a specific, unequivocal command" placed on the agency to take a "discrete agency action," and the agency has failed to take that action. *Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 63-64 (2004). The agency action must be pursuant to a legal obligation so clearly set forth that it could traditionally have been enforced through a writ of mandamus. *Vietnam Veterans of America v. Central Intelligence Agency*, 811 F.3d 1068, 1075-1076 (2016), *accord South Carolina*, 907 F.3d

at 761.

The record here is clear that the Agency did, in fact, take "discrete agency action" by issuing the final administrative decision of the Secretary, denying the Medicare reimbursement claims at issue. (CAR 14-22). Because there is no record evidence the Agency failed to take the required action here, Vein & Wellness has no basis to compel agency action under 5 U.S.C. § 706(1).

2. The Agency Action at Issue Was Not In Excess of Statutory Jurisdiction, Authority, or Limitations, or Short of Statutory Right in Violation of 5 U.S.C. § 706(2)(C).

Vein & Wellness alleges the Secretary's final administrative decision violated 5 U.S.C. § 706(2)(C) because it supposedly was in excess of statutory jurisdiction, authority, or limitations, or short of statutory right. Compl. at ¶¶ 37-38. However, the Secretary did not exceed his statutory authority. Congress has explicitly delegated to the Secretary the authority to decide whether a particular medical service is "reasonable and necessary" under the Medicare program. *See* 42 U.S.C. § 1395ff(a). Also, the Secretary's decision to deny Medicare Part B claims because they are not reasonable or medically necessary is discretionary. *Heckler*, 466 U.S. at 617 (holding that the Secretary's decision as to whether a particular medical service is "reasonable and necessary" and the means by which she implements her decision, whether by promulgating a generally applicable rule or by allowing individual adjudication, are discretionary decisions). Given this context, there can be no excess of statutory authority.

Courts have consistently found no excess of statutory authority in violation of 5 U.S.C. § 706(2)(C) where an agency has a clear delegation of authority and/or the agency action is committed to the agency's discretion. *See e.g., Baptist Mem'l Hosp.-Golden Triangle, Inc. v. Azar*, 956 F.3d 689, 693 (5th Cir. 2020) (Secretary did not exceed statutory authority in issuing final rule to clarify hospitals' "costs incurred" for purposes of disproportionate share hospital

payments because it was within Secretary's delegated authority to interpret "costs incurred").[12] Thus, in rendering an individual adjudication decision to deny medical claims under Part B of the Medicare program because they were not reasonable and medically necessary, the Secretary has clearly not exceeded his authority.

3. The Agency Action at Issue Was Not Without Observance of Procedure Required by Law in Violation of 5 U.S.C. § 706(2)(D).

Vein & Wellness alleges the Secretary's final administrative decision was issued without observance of the procedure required by law in violation of § 706(2)(D) of the APA. According to Vein & Wellness, the Secretary's final administrative decision did not comply with applicable procedural requirements because the decision improperly went beyond the issues presented to the ALJ. Compl. at ¶ 40. The APA requires a reviewing court to "hold unlawful and set aside agency action . . . found to be . . . without observance of procedure required by law." 5 U.S.C. § 706(2)(D). Here, there was no violation of § 706(2)(D) of the APA because there is no indication the Secretary's final administrative decision was issued without observance of procedure required by law.

The applicable regulations limit the Council's review "of an ALJ's or adjudicator's actions to those exceptions raised by the party in the request for review." 42 C.F.R. § 405.1112(c). Here, CMS was the party requesting review. (CAR 23-163). Consequently, the MAC review was limited only to the exceptions CMS raised. Although Vein & Wellness argues the Council should be limited only to the issues before the ALJ, the regulation at 42 C.F.R.

[12] The *Baptist Mem'l Hosp.* court utilized *Chevron*'s two-step framework in considering the challenge to the administrative final decision. While *Chevron*'s framework is technically inapplicable here because the relevant Agency interpretation was not issued through notice and comment proceedings, Congress has clearly delegated authority to the Secretary to make such decisions within his own discretion. For this reason, though *Chevron* deference is inapplicable, its framework remains useful, and the Court should find that the Secretary did not exceed his statutory authority in denying the medical claims here.

§ 405.1112(c) makes clear that the Council is fully authorized by the regulation to consider the exceptions CMS has raised.

Moreover, the regulations provide that the Council's review of the ALJ's decision is *de novo*. 42 C.F.R. §§ 405.1108(a) and 405.1110(c)(2). Additionally, the Council is specifically authorized by the regulation to "consider all of the evidence in the administrative record." 42 C.F.R. §§ 405.1108(a). "Upon completion of its review, the Council may adopt, modify, or reverse the ALJ's or attorney adjudicator's decision or remand the case to an ALJ or attorney adjudicator for further proceedings." *Id.*; *see also* 42 C.F.R. § 405.1128.

Furthermore, it should be noted that Vein & Wellness has not been prejudiced in any way by the Council's decision that the claims at issue were not reasonable or medically necessary. The original basis for the denial of the claims was the CMS contractor's determination the claims were not reasonable or medically necessary. (*See* Ex. 3 (citing to Redetermination Requests, all of which describe the original basis for the denial and the provider's right to submit evidence and/or information to rebut the claim denial)). Accordingly, Vein & Wellness already had ample opportunity to submit evidence and/or information disputing CMS's position that the services at issue were not reasonable and medically necessary. Indeed, the regulations governing the Redetermination and Reconsideration processes required Vein & Wellness to submit evidence along with its Redetermination and Reconsideration requests. *See* 42 C.F.R. § 405.946 (requiring the party requesting Redetermination to "explain why it disagrees with the contractor's determination and should include any evidence that the party believes should be considered by the contractor in making its redetermination"); 42 C.F.R. § 405.966 ("When filing a request for reconsideration, a party should present evidence and allegations of fact or law related to the issue in dispute and explain why it disagrees with the initial determination,

including the redetermination.")

In sum, Vein & Wellness's claim that the Secretary's final decision violates § 706(2)(D) of the APA fails because there is no indication or evidence the decision was issued without observance of the procedure required by law.

4. This Court Has No Jurisdiction to Grant Attorney's Fees, Costs, or Damages.

In its Complaint, Section V "Prayer for Relief," Vein & Wellness asks this Court not only to review the Secretary's final administrative decision but, also to award attorney's fees, costs, and other relief (including nominal damages). Compl. at 7. However, 42 U.S.C. § 405(g) (which is incorporated by the jurisdictional grant at 42 U.S.C. §1395ff(b)) limits this Court's jurisdiction only to enter a judgment affirming, modifying, or reversing the decision of the Secretary of the United States Department of Health and Human Services. Accordingly, this Court has no jurisdiction to grant the requested relief for attorney's fees, costs, and other relief (including nominal damages).

VI. CONCLUSION

The Secretary's final administrative decision is both legally correct and supported by substantial evidence. As a result, the Secretary's final administrative decision should be upheld affirming the determination of the overpayment against the Plaintiff.

Respectfully submitted,

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